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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/527,097	03/09/2005	Hans Smola	112701-598	3805
29157 7590 01/25/2010 K&L Gates LLP P.O. Box 1135 CHICAGO, IL 60690				
EXAMINER				
SUTTON, DARRYL C				
ART UNIT		PAPER NUMBER		
1612				
NOTIFICATION DATE		DELIVERY MODE		
01/25/2010		ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

chicago.patents@klgates.com

### Office Action Summary

**Application No.**

10/527,097

**Applicant(s)**

SMOLA ET AL.

**Examiner**

DARRYL C. SUTTON

**Art Unit**

1612

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 01 October 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) 1-9, 12 and 13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 10 and 11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/GS/US)  
Paper No(s)/Mail Date \_\_\_\_\_

- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

This Office Action is in response to the amendment filed 10/01/2009. No new claims have been added.

Applicant's arguments filed 10/01/2009 have been fully considered. Rejections and/or objections not reiterated from previous Office Actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of rejections and/or objections presently being applied to the instant application.

The Examiner would like to point out that Applicant elected (a) carnitine and (b) vitamin C in a response dated 03/05/2008. Therefore, deletion of L-carnitine form claims 10 and 11 effectively cancels the election of species. The Examiner is considering the next species, i.e. creatine, for examination.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hamilton (US 2001/0043983).

Hamilton teaches compositions to meet the needs of aging pets and other animals. The compositions include R-lipoic acid and creatine, which fight age related declines in mitochondrial function and result in less signs of aging (Abstract). Mitochondrially active antioxidants such as vitamin C and lipoic acid have been used as nutritional supplements and in dietary prophylaxis and therapy [0012] and [0023]. Lipoic acid has been used in applications to improve skin [0012] and [0027]. A daily dosage of lipoic acid is about 5 mg to 8 g [0028]. Creatine has also been used in applications for treating skin changes associated with intrinsic and extrinsic aging [0014]. A suitable dosage of creatine for pets is about 0.15 g/day to 25 g/day and preferably 0.5 g/day. The nutritional value of foods for senior dogs can be improved by addition of at least 0.1g of R- $\alpha$ -lipoic acid and at least 0.2 g of creatine daily.

Hamilton does not teach that administration of a specific embodiment of a combination of about 1 mg to about 1 g per kg of body weight per day of creatine and an antioxidant to improve skin quality or restore skin age-related alterations.

At the time of invention, it would have been obvious to administer to an aging dog a supplement comprising creatine at its preferred dosage, i.e. 0.5g/day, and lipoic acid at amounts of about 5 mg to 8 g to fight age related declines in mitochondrial function which results in less signs of aging. The amount of creatine corresponds to treating a 0.5 to 500 kg dog; and the amount of lipoic acid antioxidant corresponds to treating a 0.005 to 8000 kg dog. Accordingly, a 9.1 kg, i.e. 20 pound, dog would preferably be

administered 0.549 g per kg of bodyweight of creatine per kg of bodyweight per day along with the lipoic acid. Since the amounts of creatine and the method steps are substantially the same, the physiological activity of the compound would reasonably be expected to be the same, i.e. stimulating metabolism of a cell; and stimulating production and deposition in skin of glycosaminoglycans.

Applicants allege that ability of antioxidants and nutrients which stimulate energy metabolism to improve skin quality by stimulating the production of glycosaminoglycans represents a surprising results and cites page 1, paragraphs 16 and 18 as support of the alleged surprising result.

The Examiner has not been able to find the support for the allegations on page 1. Applicant's Example 1 relates to the stimulated glycosaminoglycan content in the skin. However, Example 1 does not show the claimed surprising results since Applicant has not made a comparison with the closest prior art. As disclosed above, Hamilton teaches compositions comprising creatine within the amounts claimed and an antioxidant which is administered to decrease signs of aging in animals. This would have been an appropriate invention for comparison.

After analyzing, even assuming arguendo that unexpected results have been found, the claims would not be commensurate in scope with those showings. In Example 1, Applicant has data on the use of L-carnitine and a cocktail of antioxidants, which has been deleted from the claims; has only used starch and sucrose carbohydrates, not any carbohydrates or creatine, fatty acids, cardiolipin, nicotinamide

or combinations thereof in combination with a cocktail of antioxidants, i.e. Diet B; has not provided weight ratios of the formulation of carbohydrates and antioxidants, i.e. Diet B; has used a cocktail of antioxidants, not any one antioxidant; and does not disclose the dosage per bodyweight per day that is administered; has provided data on increased GAG in skin, not provided any actual data on improved skin quality or the restoration of skin age-related alterations. Accordingly, the claims are much broader in scope.

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later

than SIX MONTHS from the date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darryl C. Sutton whose telephone number is (571)270-3286. The examiner can normally be reached on M-Th from 7:30AM to 5:00PM EST or on Fr from 7:30AM to 4:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass, can be reached at (571)272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Darryl C Sutton/  
Examiner, Art Unit 1612

/Frederick Krass/  
Supervisory Patent Examiner, Art Unit 1612